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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,257	04/11/2002	Richard Charles Trembath	3548 P 002	7815

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EXAMINER

SAKELARIS, SALLY A

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/701,257

**Applicant(s)**

TREMBATH ET AL.

**Examiner**

Sally A Sakelaris

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 14, 15, and 16 drawn to the S gene, primers, and a test kit(Subject to further restriction see below).

Group II, claims 2-13, and 17 drawn to a method of for determining the susceptibility of a patient to psoriasis through nucleic acid sequence analysis(Subject to further restriction see below).

Group III, claims 18 and 19 are drawn to methods for using the S gene in the manufacture of a medicament for the treatment of psoriasis.

Group IV, claim 20 is drawn to a polypeptide.

Group V, claims 21 and 22 are drawn to a method for determining the susceptibility of a patient to psoriasis by comparing protein expression patterns.

Group VI, claims 23 and 25-27 are drawn to a diagnostic method wherein an antibody specific against corneodesmosin is used as a diagnostic.

Group VII, claim 24 is drawn to a kit containing an antibody.

1. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the first mentioned products of claims 1, 14, 15, and 16 is

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considered to be the S gene. However, Zhou and Chaplin(PNAS 90, 1993 Pgs. 9470-9474. teach the S Gene cDNA consisting of 2547 bp and the predicted amino acid sequence shown in their figure 4. The reference further teaches that the S Gene may also “contribute primarily to the pathogenesis of this common disorder” psoriasis.(Pg. 9470) As the product of Group I or the method of group II do not represent a contribution over the prior art, the claims lack a special technical feature. Thus, the technical feature linking the recited groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Furthermore, the product of claims 20 and 24 are a polypeptide and antibody respectively and as such do not share the same special technical feature as the other nucleic acid products of claims 1, 14, 15, and 16, and as a result an additional lack of unity exists in the claims.

Polynucleotides, polypeptides, and antibodies are characterized by different structures and as a result different functions, the nucleic acid is composed of nucleotides joined by phosphodiester linkages whereas proteins are composed of amino acids linked by peptide bonds, while the antibodies are composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows the antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. As the products do not share the same special technical feature, the claims lack a special technical feature. Thus, unity is lacking.

Furthermore, it is also noted that the particular products that comprise groups I, IV, and VII are not joined by a common structure with one another. In this case, the products are each separately drawn to nucleic acid molecules, polypeptides, and antibodies and as stated above the products do not share the same special technical feature. Thus, there is no common structure that

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joins the particular products that comprise groups I, IV and VII.

Lastly, the claimed methods of Groups II, III, V and VI have different objectives, require different process steps and require the use of different reagents. The method of Group II requires the steps of nucleic acid isolation and analysis. The method of Group III requires the steps involved in producing a medicament for the treatment of psoriasis. Group V requires steps for comparing polypeptide expression. Finally Group VI involves a diagnostic method using antibodies that represents its technical feature. In addition to the differences in objectives, effects, and method steps it is again noted that the claims do not share a special technical feature throughout because of different biomolecules with different structure and functions and thus lack unity of invention.

#### **ADDITIONAL SEQUENCE REQUIREMENT**

2. Additionally, as unity of invention has been broken it is furthermore required to elect a single haplotype from claims 3-13 and further a single primer pair from claim 14 of the S gene for further prosecution. For example, if applicant elects Group II for future prosecution, they must also elect a single haplotype including a single position at each of the 3 positions they claim of the S gene. Because each sequence, whether comparing polynucleotides with each other or polynucleotides with polypeptides, are different and as a result have different structures and functions. Applicant must elect a group for prosecution and furthermore a single haplotype or primer pair (depending on their elected group) relevant to the elected invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter and because these inventions require different searches that are not co-extensive,

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examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sally Sakelaris



8/20/2004



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